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RECORD OF ORAL HEARING

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte THOMAS R. ADAMS, et al.

Appeal 2007-1141
Application 08/113,561
Technology Center 1600

Oral Hearing Held: February 12, 2008

Before DONALD E. ADAMS, DEMETRA J. MILLS, and LORA M. GREEN, *Administrative Patent Judges*.

ON BEHALF OF THE APPELLANTS:

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The above-entitled matter came on for hearing on Tuesday, February 12, 2008, at the U.S. Patent and Trademark Office, 600 Dulany Street, Alexandria, Virginia, before Virginia Johnson, Reporter.

MS. BOBO-ALLEN: Calendar Number 5, Appeal Number 2007-1141. Mr. Hanson.

JUDGE ADAMS: Thank you. Good morning, Mr. Hanson.

MR. EISENBERG: Good morning.

JUDGE ADAMS: Welcome back.

MR. HANSON: I see some familiar faces.

JUDGE ADAMS: Absolutely. We're familiar with your case, and you have 20 minutes.

MR. HANSON: Adams, et al. First off, I just want to say Good Morning, thank you for your time today. I, I appreciate it, and may it please the Board. Again, my name is Rob Hanson and I represent DeKalb Genetics Corporation. There's of course two issues; the written description and enablement. Before I get into that just briefly I did just want to mention that the parent case or actually the child case of this application has issued and has similar claims, and I just wanted to call that to your attention because it has some of this fatty acid desaturase limitation that we'll be talking about today and I understand that each case is decided on its own merits, but, you know, by the same token there's certainly an interest in, in uniform prosecution.

The child application was a continuation of this case issued as Patent 6803499 on October 12th, 2004, and I won't go -- get to, to far into that, but basically Claim 1 of this patent is directed to a process for producing a product for animal or human consumption. The relevant element of which would be providing a feral transgenic maize plant that has a heterologous DNA encoding, a marker gene and a DNA encoding of fatty acid desaturase.

And so, I would ask if you would please to take a look at that. And, again, of course I do understand that each case is on its own merits, but it has the same exact specification and it was the essentially the same limitation there.

Moving on, the, the written description and the enablement rejections -- I thought I'd start with the written description rejection. Really there's, there's one principle point that I'd like to emphasize today, which would be that the, the rejections that that brought us here were based on the wrong legal standard which would be the Eli Lilly Standard; whereas the correct standard would be the, the Capon v. Esher Standard which was the case was decided actually after the, after the final office action.

The Eli Lilly chain, chain of cases, of course, would apply to this situation where a novel nucleic acid or a novel compound is claimed and, you know, we certainly don't dispute the validity of that whole thing or the Rochester case or the Bayer case or the Amgen v. Chugai case, which are all essentially involve the same situation. The Capon decision, basically the, I'm sure you're all familiar, but there was a chimeric molecule was at issue and an interference. And, the chimeric molecule involved known components and the, the rejection from the Board or essentially the Board held that there's no written description because those individual components were not adequately described. It went to the Federal Circuit and the principle issue was that those individual components were known. So, those individual components that made up the chimeric molecule were known. Federal Circuit said that because of that, this is actually a different situation. And, they discussed many of the same cases that the Examiner has relied here upon principally the Eli Lilly decision. And so, really, the situation here is different because the fatty acid desaturase genes are well known in

the art and that's -- that was the purpose behind these Exhibits A through G. And, you probably do know Exhibit F, I believe was published shortly after the priority day, August 1993, but was filed before hand. But, these do show different fatty acid desaturases that were, that were known in the art.

Moving on to the enablement rejection briefly, the principle points I'd like to make here are, you know, number one, that I don't think that there's any evidence in the record that would support the rejection. And, number two, we have affirmatively demonstrated enablement based on the Ursin Declaration as well as the specification.

Point one, the Examiner relies in making the rejection on two references principally which would be the Post Beitten Miller reference and the Stephanopoulos reference. Post Beitten Miller reference, if you look at this, it was actually an acyl carrying protein. A spinach acyl carrying protein that was expressed in tobacco. The acyl carrying protein is not a fatty acid desaturase, it's actually a cofactor.

If you look in the abstract of Post Beitten Miller. It's a cofactor that's apparently regulates various different components and so it's by no means a desaturase. And, it's, you know, that would be greatly distinct from the situation where fatty acid desaturase was, for example, where you would be expressing one enzyme that has one statin. And, also the Post Beitten Miller does in fact show that the elevated -- they were able to elevate this cofactor two to three fold and they showed that it participated in fatty acid metabolism. They did not show a change in oil and all I can assume from that is that is was not an eliminating factor. But, again, it's not a fatty acid desaturase and it's greatly distinct from the step, from the simple step where you express a fatty acid desaturase that would desaturate one step. So, take

a, a saturated molecule, desaturate one step, remove a carbon at one of those steps would change the oil composition and I'll discuss this in the, in the context of the Ursin Declaration in a minute.

Stephanopoulos is just a general review. Again, this doesn't really involve fatty acid desaturase, and it's cited for the proposition. Generally, it's, it's kind of pie in the sky about metabolic engineering, and again, if, if you look at this as just kind of a scientific article. And, if anything, it lays out a general scheme for how you pick a particular location in a metabolic pathway to manipulate. It doesn't say anything about difficulty of fatty acid desaturation. And again, we're talking about one step. So, it would just be one desaturation. One particular desaturated carbon desaturated.

I think this is, this is well illustrated by the Ursin Declaration.

JUDGE ADAMS: Before you go there, what, what phenotypic change are you looking for?

MR. HANSON: Well, it would be a -- typically a change in the saturation of a fatty acid.

JUDGE ADAMS: So, why is the Examiner going off on this idea of increasing cold tolerance, plant heights, yield, insect resistant, flower color?

MR. HANSON: I, I don't know, and I want to be respectful to the Examiner and so I said, you know, Applicants are puzzled. I think are the words that I used, and so I didn't understand that, but a desaturase would desaturate a fatty acid molecule at a specific location. If it's at Delta-6, it would desaturate at the 6th carbon over. If it's Delta-9, etcetera, etcetera. And, that, that was known in the art. And so, yeah, I didn't understand what, you know, what that was about, but it's --

JUDGE ADAMS: So a person of ordinary skill in the art reading the specification and looking at your claims and attempting to practice this claimed invention, would look to some difference in this fatty acid synthesis as the phenotypic change. Is that what you're saying?

MR. HANSON: Yeah, I think it would be an oil. Oil composition --

JUDGE ADAMS: Notwithstanding that there might be some other phenotypic change like, you know, it might change the flower color or something like that, but you're looking at just -- is there a difference in the fatty acid content?

MR. HANSON: Yeah, and interestingly I didn't, you know, I, I don't know what the history was in the child case that I mentioned just a, just a minute ago. But, the child case mentions oil quality or quantity. I mean, that language is fine with me and I would be glad to put that in there, but that was never an issue in prosecution. But, generally, the desaturase is known in the art. You know, as shown in the exhibits, it relates to oil.

JUDGE ADAMS: There's never been a real issue as to what transformation method you use here, right? It's -- you can use whatever was known in the art at the time the invention was made.

MR. HANSON: Exactly, and that's -- well, that -- and that's a good lead into the Declaration because one of the issues in the, in the Declaration was -- well the Declaration shows expression of two fatty acid desaturase as a Delta-6 and a Delta-15 desaturase. and, the Examiner -- the reason the Examiner held that this does not show enablement, there were two things; is the Declaration involved transformation by agribacterium mediated transformation which, which is a different technique then, then is

in the specification, but the Examiner is not contesting the fact that transformation was enabled. And so, there's really no issue in terms of whether you can get the gene in there. What's relevant is what happens once the gene is in there because it doesn't matter how you got the gene in there to whether it expresses or not. And so, that was just agribacterium was chosen because it'd been found -- I mean, I mean, the reality of it is that agribacterium works better because you get less -- you get more simple transformation in events; single copy events. When you do microprojectile bombardment, you have to pick out the ones that aren't -- that don't have multiple copies and it's more difficult to get it through regulatory if you have five copies of a gene then if you have one copy. That's why, that's why they chose it, but it really doesn't matter because the specification, for example, shows 267 different transformation events. And again, it's not contested that there's no problem getting the gene in there.

And the other, the other reason the Examiner said --

JUDGE ADAMS: Well, getting, getting a desaturase gene or getting some other type of gene?

MR. HANSON: Well, the specification fully enables any gene. I think there were 13 different very diverse genes that were shown to be expressed in the, in the specification.

JUDGE ADAMS: It never showed a specific exemplification of a desaturase?

MR. HANSON: That's correct.

JUDGE ADAMS: Not that you need that, but it just --

MR. HANSON: Exactly.

JUDGE ADAMS: -- just so you declare it, right?

MR. HANSON: That's correct. And, well the other issue was that the Examiner said, well you have two; you expressed two different fatty acid desaturases. And, I said well --

JUDGE ADAMS: In your Declaration?

MR. HANSON: Exactly. And, so that was a contention, you know, by the Examiner: well, that's different because you expressed two. Well, if you look at the examples, it is clear that or if you look at that Declaration, it's clear that both desaturases were functioning. And, you can tell that from the change in the oil composition; for example, the specification -- I'm sorry, the Declaration says that explains that linolenic acid was decreased and linolenic acid is a carbon-9 and carbon-12 desaturated fatty acid with, I believe, it's 18 carbon. And, an increase in gammalinolenic acid, which is desaturated carbon-6 and sterodonic acid, which is desaturated at carbon-15. And so, what you see there is an increase in carbon-6 desaturation and carbon-15 desaturation which is consistent with the activity of each enzyme.

JUDGE ADAMS: I'm a little confused about the Examiner's comment there as well because in your impression is your claim limited to transfecting with just one desaturase gene, or does it say comprising --

MR. HANSON: No.

JUDGE ADAMS: -- of just --

MR. HANSON: Comprising. I think, I think --

JUDGE ADAMS: So, it could be one or two or how ever many you want to put in there?

MR. HANSON: Correct, and I think, I think it might -- I think the Examiner is trying to make the point that we had to have two to get a

phenotype. And again, the reason, the reason the two were used, just so you know, is, is that the, the sterodonic acid is a more healthful oil and that was the commercial goal. I mean, I would have -- you know, it would have been easier if we would have just said okay let's just put, you know, single ones, but there, there was no purpose and so these were put into a single -- into corn oil.

If you only put one of the -- if you only put Delta-6, then you'd get this increase in gammalinolenic acid, but if you put both you get the sterodonic acid which has the carbon-6 and the carbon-15 desaturation.

So, based on that -- I mean the, the Declaration does in fact show both of these desaturases function. You know, Dr, Ursin explains that the phenotype that you see in the cell is consistent with the activity of desaturase. So, it's a known as a delata-6 desaturase. You get delta -- you get six -- carbon-6 desaturation. If it's known as a delta-15 desaturation, you get carbon-15 -- I'm sorry, delta-15 desaturation, you get a carbon-15 desaturation.

So, essentially, that shows, you know, pretty much the opposite of what, what the Examiner has contended. Another point I'd like to make is, you know, the Examiner says well, you have no more working example of four desaturation. Well, that's, that's true, but that also brushes past the extensive teaching in the specification. And so, you know, there's 43 and I just jotted it down here, because it's hard to remember all the, all the numbers because there are such, such large numbers, but 267 different transformation events were described in the specification. Forty-three working examples. The genes that were expressed, if you look at the nature of those genes, I think it'll be clear why one who skilled in the art reading

this specification would have an expectation and an understanding that the desaturase would, if properly expressed, these genes, a UIAD gene which is a GUS, a selectable marker -- I'm sorry, screenable marker. It makes a blue color; betagalactosidas, I think is how you detect that. A bar gene for biallifis (phonetic sp.) resistance. It's a herbicide. Hygromycin resistance, that's a selectable marker. And, arrow A gene for glyphosate herbicide resistance, that's Round Up, Round Up Herbicide. A BT crystal protein for insect resistance and a z10 zean (phonetic sp.) seed storage protein gene. Those were all expressed in transgenic plants.

JUDGE ADAMS: So, notwithstanding the fact that there is no working example of the transformation of the desaturase, you're, you're position is no one of ordinary skill in the art would question that you wouldn't be able to express the desaturase gene or first transfect the desaturase gene -- see it expressed given the same methodology for these other genes that you've, you've used.

MR. HANSON: That's exactly right. One, one of skill in the art having read and understood the specification would, would have no doubt. And again, you know, not to belabor the point, but they also, you know, the examples show a c1 anthocyanin gene, that's a red coloration. A gene that causes red coloration, a leuciforase fluorescent marker gene. Potato and tomato protein inhibited -- proteinase inhibitor genes. An MTLD stress, stress tolerance gene, and then finally a Delapon herbicide resistance gene.

I think the most important thing about all these different examples is that they're completely diverse. These are various different -- these genes have various different functions. They're kind of all over the map in terms

of the, the type of genes that are expressed, and I think that, you know, that makes it clear that one skilled in the art would have had an expectation that the desaturase would function properly.

JUDGE MILLS: You would use the promoter as described in the specification for the other genes to read the desaturase gene?

MR. HANSON: Right, I think the, the -- in the working example or in the Declaration, I think it was a globulin promoter, which I believe -- I think the -- if you look at the exhibit, I think it mentions --

JUDGE MILLS: Is that Ursin?

MR. HANSON: Yeah, it's Exhibit H to our brief. And, in Paragraph 5, it says that the globulin promoter was used; see Table 3, regulatory sequence 123. So, if you look in Table 5 has all these regulatory elements listed out. Not Table 5. Is that right? Table 3. And, actually, if you look at that table, I believe, I believe that table shows -- yeah, Table 3 spans a few pages here and it shows all the different constructs. I believe there's a total of over 100 different constructs that are described there that have various different components. I believe there's something in the, the order of 27 different types of regulatory elements that are, that were used, and these would include promoters, terminators, enhancers, the globulin promoter. Yeah, it looks like Component 123. It says the globulin promoter and terminator sequences from Zea mays Belanger and Kriz. 1991. And, I think that was used -- I think that's a, a seed or embryo specific promoter which is where the most of the oil is, is generally in the, in the seed. And, I think that's why that was, that was chosen. And interestingly, I think that if you look at the Stephanopoulos paper, I think they looked -- they were looking in leaves which is a little bit different. I, you know, which was one

thing I didn't, I didn't understand because typically the -- that's not the seed oil is generally where you would find the oil and the seed is where you find the oil in a plant.

Really, the, you know, the, the last point that I really want to make was, you know, the extensive, extensive teaching that is in the specification; Table 2 for example, sows the transformation in 37 different types of maize cultures. Table 3, again, we just, we just looked at a minute ago, has over 100 constructs in it; various different regulatory elements, various coding sequences. One who has skill in the art that had possession of the working examples, you know, of this, of this teaching, could readily plug in the known desaturase and, and achieve, achieve a detectable phenotypic change. Examples 8 to 11 show microprojectile bombardment of different cultures of maize cells and optimization. Example 12, bombardment of immature embryos in expression of the anthocyanin marker gene. Example 13 electroporation of two different cultures to achieve transformation. Example 14 electroporation of embryos. Example 15 is silicon fiber mediated transformation of corn cells. Example 16 is selection of bialaphos glyphosate hygromycin, pretty distinct selectable agents. Example 18 is GUS, GUS expression, and that's a screenable marker or color marker. Example 27, leuciferase screening, fluorescent, fluorescent marker. Examples 30 to 31, shows regeneration of transgenic plants in great detail.

JUDGE ADAMS: You don't, you don't need to go through each one.

MR. HANSON: Yeah, I don't want to be belabor the point, but --

JUDGE ADAMS: I didn't know if you were reading into the

record or --

MR. HANSON: No, and I don't want to put you to sleep --

JUDGE ADAMS: Yeah, really.

MR. HANSON: -- but, by the same -- you were -- yeah, I know, it's early in the morning, I don't want to ruin your day, but I don't want, but I don't want to short sell the specification because --

JUDGE ADAMS: I understand.

MR. HANSON: -- I think if you read the, if you read the Examiner's answer, I think that the point that I, I don't want to simply let brush by is that while you didn't have a working example for desaturases, you know, end of story. I just want to make sure that, that --

JUDGE ADAMS: No, right. That is why I kept harping that notwithstanding that you don't exemplify the transformation over the centuries. You have other genes that you do exemplify, and there is nothing that would suggest that if you can do it with this, you can't do it with desaturase. Is that your point?

MR. HANSON: Exactly, exactly. And so, I just want to make, make sure. Yeah, I know, I know, but it wasn't fun for me reading it off either, but I figured I owed it to --

JUDGE ADAMS: I'm glad I stopped you.

MR. HANSON: I owed it to my client. Thank, thank you for doing that. Like I say, I tried my hardest.

JUDGE ADAMS: We got you.

MR. HANSON: And, really, I mean, that's, that was the point that I wanted to make and so I'll spare you. And, I think, you know, if

there's not any questions, that was the -- those are basically the points that I wanted to make.

JUDGE ADAMS: Just to reiterate one last time, we're not necessarily looking for a phenotypic change at the flower level or something like that. We're looking for a phenotypic change in terms of a change related to the desaturase, right?

MR. HANSON: That --

JUDGE ADAMS: That it's going to change the fatty acid content itself.

MR. HANSON: I think that's, I think that's a fair characterization, yeah. That's what --

JUDGE ADAMS: I mean, it might have other effects, but at a minimum it has to do that, right?

MR. HANSON: Some, some change in oil composition.

JUDGE ADAMS: Because that's what desaturases do, right?

MR. HANSON: Yes, that's what they do.

JUDGE ADAMS: Any questions?

JUDGE MILLS: No, I don't have any.

JUDGE ADAMS: Okay.

MR. HANSON: Thank you, very much.

JUDGE ADAMS: I'm going to ask you to hang on one second and have our transcriptionist ask you spellings and your name and things like that.

MR. HANSON: Okay.

(Whereupon, the proceedings concluded.)